

Effectiveness of Needleless Vial Adaptors and Blunt Cannulas for Drug Administration in a Microgravity Environment

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Introduction:

The current system for injectable medications aboard the International Space Station (ISS) experienced a materials failure. This failure now requires a new injectable medications system to be put in place and flown.

The desire is to fly the new system in the original manufacturer's packaging. In doing so, it will allow compliance with United States Pharmacopeia (USP) guidelines as well as minimize the frequency of resupply due to medication expiration. Prefilled syringes are desired, however, the constant evolution of pharmaceutical packaging within the health care market requires flexibility in design. If the medications must be supplied in a vial, a system is required that will allow for the safe withdrawal of medication from the vial into a syringe for administration. Two microgravity flights were conducted to evaluate hardware and fluid issues related to withdrawal of medications from a vial to syringe.

Methods:

A market study was conducted with two versions of a blunt cannula and two versions of needleless vial adaptors selected for evaluation. Ground-based and reduced gravity flight evaluations were conducted using injectable medications similar to those flown currently on the ISS. Microgravity flight evaluation included 60 total parabolas spanning two flights

Parameters assessed included:

- Ease of hardware insertion through vial septum
- Air/Fluid isolation within the medication vial and syringe
- Ability to withdraw the required amount of medication

Results:

Ease of Hardware insertion through vial septum – vial adaptors:
Given the limitations of space within the ISS medical kits, it is desired to fly only one size vial adaptor to interface with all medication vials regardless of size. The cap vial adaptor, with its' smaller diameter spike was markedly superior in perforating the rubber septum of a vial without causing displacement that may lead to leakage. The spike vial adaptor diameter was so large that, in some instances, it totally displaced the septum of the vial causing leakage and risk of drug contamination. Neither adaptor was capable of locking securely (grasping to sides of vial top) with all size vials tested (2mL – 30mL vials).

Ease of Hardware insertion through vial septum – blunt cannulas:
The plastic blunt cannula performed consistently well with septum perforation using minimal force due to the narrowed tip, which facilitated an efficient, non-coring pierce to the septum. The blunt metal cannula required greater force to push it through the vial septum. A larger diameter metal cannula (17G) requires greater force, while a smaller diameter (21g) increased the risk of bending the metal cannula during insertion. The force required for insertion also causes a noticeable disruption of fluid, thus negating the effects of a good fluid/air separation manoeuvre in microgravity.

Results:

Fluid Isolation in the medication vial:

Air/ fluid isolation maneuvers were used to move the medication to the septum end of vial. This isolation may be achieved in multiple ways based on the experience of the astronaut with fluid management in microgravity. If vial adaptors/blunt cannula or syringe assembly is inserted into the vial before fluid isolation commences, the stability of this assembly should be considered in an effort to limit the risk of 'slinging off' of the vial during isolation.

Alternatively, fluid isolation can be performed prior to attaching the syringe/vial adaptor assembly.

Terrestrial practices for medication withdrawal from a non-vented vial require injection of an equivalent amount of air as the expected medication volume prior to withdrawing liquid. In microgravity, this action is still valid, however the injection of additional air into the vial creates a multitude of micro bubbles and increases the volume of medication mixed with air that then must be withdrawn to achieve the desired drug volume in syringe. This practice is more likely to be required when using vials >30mL in size and injection volumes >10mL. It is felt that based on the microgravity flight, the practice of air injection is more of a hindrance than help.

Results:

Air / Fluid Separation in Syringe: Due to dead space within vial adaptors, blunt cannulas, and syringes, some air will inevitably be mixed into medications as they are withdrawn into a syringe, despite effective fluid isolation in the vial. This air, combined with any micro bubbles that are possibly still in the solution, will require a second effort to isolate fluid in the syringe before the medication can be administered. Selection of a syringe size larger than the volume required is considered to be helpful so that a larger volume than necessary may be withdrawn. This can be followed by fluid and air isolation in the syringe with the extra air ejected before administering the medication.

Results:

Ability to withdraw the required amount of medication - vial adaptors:

Needleless vial adaptors are appropriate for use with multidose vials as their large volume puts most of the required medication volume at the location of the fixed position vial spike. However, single dose medication vials with volumes <5 mL posed a greater challenge in accessing the entire drug volume required for administration. At issue is the manufacturer's air bubble in the vial; in microgravity, this air bubble traps fluid along the sides and base of the vial despite effective air/fluid separation before withdrawal of the medication. Terrestrially, any fluid that is not immediately at the septum may be 'chased' using a needle that can be manipulated to the liquid bubble. The vial adaptors also were limiting because of their spike length in relation to the total length of the medication vial and volume of medication.

Results:

Ability to withdraw the required amount of medication – blunt cannula:

In-flight evaluation of the capabilities of the blunt cannulas was inconsistent. While the metal cannula was capable of reaching the bottom corners of the $\leq 3\text{mL}$ vials, the plastic cannula was still capable of manipulation to the sides of the vial which, with repeated air/fluid isolation attempts, enabled the withdrawal of the desired volume. However, problems with shorter than normal parabolas and the need for repeated fluid air isolation attempts provided inconsistent results that point to one device over the other. Both the metal and plastic blunt cannula were capable of withdrawing the required volume from the vials. It is therefore hypothesized that either cannula would perform as desired given appropriate time for repeated air /fluid separation.

Conclusions – Vial Adaptor :

While advantages were observed for both pieces of hardware, it was felt that the cap vial adaptor was the superior choice of the two pieces of hardware. Its advantages include the cap, which serves as a physical barrier between the septum and the environment, which would be helpful when considering that multidose vials might be restowed within the ISS Medical Kits. Additionally, its smaller diameter spike is markedly superior in perforating the rubber septum without causing displacement, thereby limiting leakage. Additionally, it has a very small dead space in comparison to the spike vial adaptor, which limits the introduction of unnecessary air into the syringe.

Conclusions – Blunt Cannulas:

Plastic tip and blunt metal cannulas both facilitate the effective removal of medication from single dose medication vials $\leq 3\text{mL}$. However, the plastic blunt cannula is preferred for its ease of perforation of the vial septum, limiting the risk of damage to the cannula or vial septum as seen with the different sizes of blunt metal cannulas.

Recommendations

If one device is required to withdraw all medications from a vial, we recommend using the plastic blunt cannula. This hardware would allow efficient access through the vial septum and the ability to retrieve a required volume from a vial.

However, if allowed, and if space for more than one access device is permitted, we would recommend the plastic blunt cannula for single dose vials and the cap vial adaptor for multidose vials. This cap vial adaptor would then provide physical protection to the vial septum while allowing multiple syringe access to the vial without repeated septum punctures.



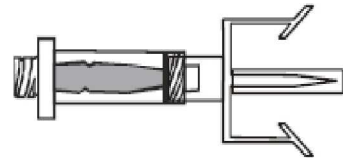
Metal Blunt Cannula



Plastic Blunt Cannula



Cap Vial Adaptor



Spike Vial Adaptor



**Tip of metal
blunt cannula**



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blunt cannula**



